K123976
Page 1 of 5

1.4 510(k) Summary of Safety and Effectiveness

MAR 2 6 2013

Submitted by:	Phuong Nguyen Manager Regulatory Affairs
Address:	Nobel Biocare USA LLC 22715 Savi Ranch Parkway Yorba Linda, CA 92887
Telephone:	(714) 282-4800 x7830
Facsimile:	(714) 998-9348
Date of Submission:	December 21, 2012
Classification Name:	System, Image Processing System, Radiology (21 CFR 892.2050)
Trade or Proprietary or Model Name:	NobelClinician
Legally Marketed Device(s):	Swissmeda Dental Planning System (K112251) The Guided Surgery Concept (K050393) Maxilim (K052424)

Device Description:
NobelClinician is a software interface for the transfer and visualization of imaging information: 3D imaging like medical or Cone Beam CT data, 2D imaging like photographic images and X-ray images. NobelClinician is used to support diagnostics and treatment planning for dental and cranio-maxillofacial treatment through the use of prosthetic-driven implant planning based on the digitized patient data and the scanned radiographic guide representing the ideal diagnostic tooth setup. The planning can be previewed using the software and a surgical template realizing the planning can be ordered.

Indications for Use:
The NobelClinician software is a software interface for the transfer and visualization of imaging information from equipment such as a CT scanner or a magnetic resonance scanner for the purposes of diagnosis and treatment planning in the dental and cranio-maxillofacial regions. The NobelClinician software can be used to design a surgical template for the purposes of aiding placement of dental implants.

Summary of testing to demonstrate safety and effectiveness:
The performance of the NobelClinician software was verified and validated following the guidance provided in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

Conclusions:
The information provided in this submission demonstrates that NobelClinician is substantially equivalent to the predicate device.

1.4 510(k) Summary of Safety and Effectiveness

Substantial Equivalence Comparison to Predicate Devices

CHARACTERISTIC	CANDIDATE	PREDICATE	PREDICATE	PREDICATE
	NobelClinician	The Guided Surgery Concept (K050393)	Swissmeda Dental Planning System (K112251)	Maxilim (K052424)
Imaging data format	DICOM	DICOM	DICOM	DICOM
Software Features	- Help assistant - Create a new patient record - Add images to a patient - Create and manage planning scenarios and treatments - Create and edit 3D Models - Create a snapshot of a viewer - Display and manipulate reslices - Define the dental curve shape - Define a new visualization for the volume model - Adding prosthetics information - Alignment of radiographic guide and patient model - Annotate structures - Diagnostic 3D visualisation for diagnostics of maxillofacial anatomy - Measure the distance between 2 points	- Help assistant - Create a new patient record - Create and manage planning scenarios and treatments - Create and edit 3D Models - Create a snapshot of a viewer - Display and manipulate reslices - Define the dental curve shape - Adding prosthetics information - Alignment of radiographic guide and patient model - Annotate structures - Measure the distance between 2 points - Measure the plane angle between 2 points - Indicate and edit nerve structures - Adding an implant to a planning and edit	- Create a new patient record - Create and edit 3D Models - Display and manipulate reslices - Define the dental curve shape - Define a new visualization for the volume model - Adding prosthetics information - Alignment of radiographic guide and patient model - Indicate and edit nerve structures - Adding an implant to a planning and edit - Adding an abutment to an implant - Manage objects in a 2D and 3D viewer - Surgical template visualization - Approve function - Create and send an order	- Help assistant - Create a new patient record - Add images to a patient - Create and manage planning scenarios and treatments - Create and edit 3D Models - Create a snapshot of a viewer - Display and manipulate reslices - Annotate structures - Diagnostic 3D visualisation for diagnostics of maxillofacial anatomy - Measure the distance between 2 points - Warning system

K123976
Page 295

1.4 510(k) Summary of Safety and Effectiveness

Substantial Equivalence Comparison to Predicate Devices

CHARACTERISTIC	CANDIDATE	PREDICATE	PREDICATE	PREDICATE
	NobelClinician	The Guided Surgery Concept (K050393)	Swissmeda Dental Planning System (K112251)	Maxilim (K052424)
	- Measure the plane angle between 2 points - Indicate and edit nerve structures - Adding an implant to a planning and edit - Adding an abutment to an implant - Manage objects in a 2D and 3D viewer - Warning system - Surgical template visualization - Approve function - Create and send an order	- Adding an abutment to an implant - Manage objects in a 2D and 3D viewer - Warning system - Surgical template visualization - Approve function - Create and send an order		
Intended use	- Diagnostics - Surgical planning for dental implants - Creation of surgical template	- Diagnostics - Surgical planning for dental implants - Creation of surgical template	- Diagnostics - Surgical planning for dental implants - Creation of surgical template	- Diagnostics - Surgical planning for dental implants - Creation of surgical template
Computer format	PC – Windows based MAC - OS	PC – Windows based	PC – Windows based	PC – Windows based
Anatomic areas	Maxilla Mandible Cranio-maxillofiacial	Maxilla Mandible	Maxilla Mandible	Maxilla Mandible Cranio-maxillofiacial

K123976
Page 385

1.4 510(k) Summary of Safety and Effectiveness

Substantial Equivalence Comparison to Predicate Devices

CHARACTERISTIC	CANDIDATE	PREDICATE	PREDICATE	PREDICATE
	NobelClinician	The Guided Surgery Concept (K050393)	Swissmeda Dental Planning System (K112251)	Maxilim (K052424)
Indications for Use	The NobelClinician software is a software interface for the transfer and visualization of imaging information from equipment such as a CT scanner or a magnetic resonance scanner for the purposes of diagnosis and treatment planning in the dental and cranio-maxillofacial regions. The NobelClinician software can be used to design a surgical template for the purposes of aiding placement of dental implants.	The Guided Surgery Concept and Teeth-in-an-Hour are indicated for the treatment of single, partially and totally edentulous jaws for placement of implant fixtures with immediate function to restore patient esthetics and chewing function. The following prerequisites must be fulfilled: - Adequate amount of jaw bone - The quality of jaw bone must be judged as adequate	Swissmeda Dental Planning System is intended for use by qualified dental professionals for Windows based diagnostics and implant planning. The software is an interface for imaging data that originates from medical scanners such as CT or DVT scanners and it is also a pre-operative software for simulation and evaluation of dental implant placement in the patient's mandible/maxilla and for surgical treatment options. Swissmeda Implant Planning System is not intended to be used in direct contact with the patient nor is it intended to be used with life sustaining devices. The planning data may be exported from Swissmeda Dental Planning System and used as input data for a special drilling device from company Georg Schick for manufacturing	Maxilim is indicated for use as a software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a CT scanner. It is also indicated for use as a planning an simulation software for surgical treatment, specifically maxillofacial treatment.

1.4 510(k) Summary of Safety and Effectiveness

Substantial Equivalence Comparison to Predicate Devices

CHARACTERISTIC	CANDIDATE	PREDICATE	PREDICATE	PREDICATE
	NobelClinician	The Guided Surgery Concept (K050393)	Swissmeda Dental Planning System (K112251)	Maxilim (K052424)
			drilling templates in a laboratory environment. The drilling template is then used in direct contact with the patient to realize the implant planning.	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 26, 2013

Nobel Biocare USA, LLC
% Mr. Phuong Nguyen
Manager Regulatory Affairs
22715 Savi Ranch Parkway
YORBA LINDA CA 92887

Re: K123976
Trade/Device Name: NobelClinician
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 21, 2012
Received: December 26, 2012

Dear Mr. Nguyen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

1.3 Indications for Use

510(k) Number K123976

Device Name: **NobelClinician**

Indications For Use:

The NobelClinician software is a software interface for the transfer and visualization of imaging information from equipment such as a CT scanner or a magnetic resonance scanner for the purposes of diagnosis and treatment planning in the dental and cranio-maxillofacial regions. The NobelClinician software can be used to design a surgical template for the purposes of aiding placement of dental implants.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health
510(k) 123976